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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/344,382	06/25/1999	SHUNICHI SOMA	050499/0101	9000

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/344,382

Applicant(s)

SOMA ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-42, 44-51 is/are pending in the application.
- 4a) Of the above claim(s) 29-42, 44 and 46-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-28, 45 and 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-42 and 44-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>22</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 22-42, 44-51 are pending. Claims 29-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in

5 Paper No. 4. Applicant's elected group I and the species that encompass continuous, systemic administration of PTH(1-34) in Paper No. 12. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 22-28, 44-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being

10 drawn to, or to the extent that they are drawn to, a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12. Claims 22-28, 45, 49, 50, 51 are being examined to the extent that they read upon the elected invention and/or species.

Claim Rejections - 35 USC § 103

15 Claims 22-28, 45, 49, 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianelly (w6) in view of Kronenberg (A1, cited by Applicants), Gardella (A7, cited by Applicants), and Sindrey (A2, cited by Applicants) and further in view of Yamasaki (A5, cited by Applicants), Collins (A19, cited by Applicants), Kamata

20 (A6, cited by Applicants), Chao (A20, cited by Applicants), and Tam (a21).

Claims 22, 49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianelly (w6) in view of Kronenberg (A1, cited by Applicants), Gardella (A7, cited by Applicants), and Sindrey (A2, cited by Applicants) and further in view of Yamasaki,

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Collins, Kamata, Chao, and Tam (a21) as applied to claims 22, 49 above and further in view of Schluter (a13). In the last Office action mailed January 24, 2003 this rejection originally stated that claims 22, 49, 51 were rejected. However, it is obvious that claim

5 rejection clearly indicates that this rejection is directed to the limitation "polyethylene glycol" and claim 50 is the only claim that recites the limitation "polyethylene glycol."

Applicant's attention is also directed to item 6 on the Office action summary attached to the Office action mailed January 24, 2003, wherein it is indicated that claims "22-28, 45, and 49-51" are rejected.

10 Applicant argues that in contrast to Gianelly, PTH was administered continuously in the presently claimed invention; that it could not have been reasonably expected that no necrotic tissue would be observed in the pressured side on day 3 of teeth separation; that the present invention is completely different from that of Gianelly with respect to

15 administration and effect of PTH. Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed.

20 Cir. 1986). Gianelly clearly teaches that it appears possible to enhance orthodontic tooth movement by the local use of parathyroid hormone (page 305, full paragraph 4). Regardless of the effect of PTH, Gianelly teaches the use of parathyroid hormone to enhance orthodontic tooth movement.

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Applicant argues that bone resorption is not synonymous with bone loss.

Applicant's arguments have been fully considered but they are not persuasive. There appears to be no factual basis on which to base Applicant's conclusion. Applicant has offered no evidence as to how to construe bone resorption as anything other than bone

5 loss. Furthermore, Attorney arguments cannot take the place of evidence.

Applicant argues that Tam establishes the unpredictability of the field and that unpredictability would not allow one to form a reasonable expectation of success and that one of ordinary skill in the art would not have expected the mechanism of bone turnover.

Applicant's arguments have been fully considered but they are not persuasive.

10 Obviousness does not require absolute predictability, only a reasonable expectation of success, i.e., a reasonable expectation of obtaining similar properties. One of ordinary skill in the art would have reasonably expected bone loss to result in tooth movement.

Applicant argues that intermittent administration of PTH increases bone volume, whereas tooth movement is promoted by intermittent administration. Applicant's

15 arguments have been fully considered but they are not persuasive. The point of this argument is unclear to the examiner, leaving the examiner unable to respond. However, there is nothing in the present specification or prior art of record to suggest that continuous administration of PTH would not increase tooth movement. The prior art teaches increasing bone resorption to facilitate tooth movement and the prior art teaches
20 that continuous administration of PTH results in bone loss. One of ordinary skill in the art would have reasonably expected bone loss to result in tooth movement.

Applicant argues that none of the cited references describes whether continuous administration of PTH increases osteoclast activity. Applicant's arguments have been

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fully considered but they are not persuasive. There is nothing in the present specification or prior art of record to suggest that continuous administration of PTH would not increase osteoclast activity. The prior art teaches increasing bone resorption to facilitate tooth movement and the prior art teaches that continuous administration of PTH results in bone loss. One of ordinary skill in the art would have reasonably expected bone loss to result in tooth movement.

Applicant argues there is no reasonable expectation that osteoclast activity will be increased by continuous administration. Applicant's arguments have been fully considered but they are not persuasive. There is nothing in the present specification or prior art of record to suggest that continuous administration of PTH would not increase osteoclast activity. The prior art teaches increasing bone resorption to facilitate tooth movement and the prior art teaches that continuous administration of PTH results in bone loss. One of ordinary skill in the art would have reasonably expected bone loss to result in tooth movement.

Applicant argues that it is not obvious that continuous administration of PTH increases tooth movement. Applicant's arguments have been fully considered but they are not persuasive. Yamasaki teaches that stimulation of osteoclastic activities and the resultant bone resorption are involved in orthodontic tooth movement (Figure 7). Collins teaches that although various orthodontic appliances may differ in their mode of action they all must ultimately achieve the same effect - namely, the resorption and apposition of alveolar bone to produce tooth movement in the desired direction (page 278, column 1, full paragraph 1), and suggest increasing the rate of alveolar resorption in order to increase tooth movement during orthodontic procedures (page 283, column 1, full

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paragraph 1). It is well known that PTH increases osteoclast activity and promotes bone resorption. See Kamata, page 412, full paragraph 1. Chao suggests that by activating alveolar bone resorption during orthodontic tooth movement a more rapid bone modeling and tooth movement could be achieved (Abstract, third paragraph; paragraph bridging pages 307-308). It has also been observed that the end result of the administration of PTH on skeletal homeostasis depends on how the hormone is administered. For the same daily dose, the bone volume shows a dose dependent increase if the daily dose of the hormone is given as one single injection. However, when the same daily dose is administered by continuous infusion with a subcutaneous miniosmotic pump, the result is bone loss. See Tam, column 3, lines 45-53. The prior art teaches increasing bone resorption to facilitate tooth movement and the prior art teaches that continuous administration of PTH results in bone loss. One of ordinary skill in the art would have reasonably expected bone loss to result in tooth movement. For one of ordinary skill in the art to choose an increase in bone volume over bone loss in order to achieve tooth movement does not make any sense in view of the cited teachings of the cited references.

Applicant argues that bone loss under continuous administration may be the result of a reduction in bone formation rather than an increase of bone resorption. Applicant's arguments have been fully considered but they are not persuasive. Whether bone loss under continuous administration is the result of a reduction in bone formation or an increase in bone resorption, one of ordinary skill in the art would reasonably expect the end result of bone loss to be the same, i.e., an increase in tooth movement.

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Applicant's discussion of Collins and an improper allegation is acknowledged.

Applicant's arguments have been fully considered but they are not persuasive. The examiner has not made such an allegation.

Applicant argues that in light of the cited references continuous administration
5 results in a different effect from intermittent administration. Applicant's arguments have
been fully considered but they are not persuasive. There is nothing in the present
specification or prior art of record to suggest that continuous infusion of PTH and the
resulting bone loss would not result in an increase in tooth movement. As discussed
previously, the prior art teaches increasing bone resorption to facilitate tooth movement
10 and the prior art teaches that continuous administration of PTH results in bone loss.

Applicant argues that a combination of many teachings cannot simply lead to an
end result. Applicant's arguments have been fully considered but they are not persuasive.
As discussed previously, the prior suggests increasing tooth movement with PTH, the
prior art teaches increasing bone resorption to facilitate tooth movement, and the prior art
15 teaches that continuous administration of PTH results in bone loss. The end result of
bone resorption is bone loss. The end result of continuous administration of PTH is bone
loss. The end result of bone loss is tooth movement.

Applicant argues that the examiner has not established a proper motivation to
combine the references, nor a reasonable expectation of success in their combination.

20 Applicant's arguments have been fully considered but they are not persuasive. As
discussed previously, the prior suggests increasing tooth movement with PTH, the prior
art teaches increasing bone resorption to facilitate tooth movement, and the prior art
teaches that continuous administration of PTH results in bone loss. The end result of

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bone resorption is bone loss. The end result of continuous administration of PTH is bone loss. The end result of bone loss is tooth movement. One of ordinary skill in the art would be motivated to make this modification because stimulation of osteoclastic activities and the resultant bone resorption are involved in orthodontic tooth movement, although various orthodontic appliances may differ in their mode of action they all must ultimately achieve the same effect - namely, the resorption and apposition of alveolar bone to produce tooth movement in the desired direction, and increasing the rate of alveolar resorption would increase tooth movement during orthodontic procedures, PTH increases osteoclast activity and promotes bone resorption, the number of osteoclasts appearing during tooth movement is related to the function of PTH activity, activating alveolar bone resorption during orthodontic tooth movement could achieve a more rapid bone modeling and tooth movement, and when PTH is administered by continuous infusion the result is bone loss. Obviousness does not require absolute predictability, only a reasonable expectation of success, i.e., a reasonable expectation of obtaining similar properties. Bone loss would reasonably be expected to result in tooth movement.

Applicant argues that Schluter does not render the claimed invention obvious. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

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Conclusion

No claims are allowable.

5 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not
10 mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

20 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

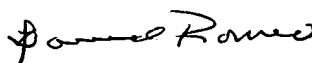
AFTER FINAL (703) 872-9307

25 IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

30 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

35 

DAVID ROMEO
PRIMARY EXAMINER
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